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Docket No.: 1691-0217PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Yuzuru UMEDA et al.

Application No.: 10/574,615

Confirmation No.: @@@

Filed: April 5, 2006

Art Unit: N/A

For: OPHTHALMIC COMPOSITION FOR
TREATING TEAR DYSFUNCTION

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT
(SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL
REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE
1.114 RCE APPLICATION)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

☒ a. Copies of cited U.S. patents and patent application publications are not included.
Copies of foreign patent documents and non-patent literature are included.

Birch, Stewart, Kolasch & Birch, LLP

MSW/sh

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.K./

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☐ b. Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☒ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☒ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

JP 6-345653 A - is discussed on page 4 of the present specification and also see the attached English abstract;

JP 2000-281563 A is cited on page 5 of the present specification and also see the attached English abstract;

WO 01/41806 A1 is cited on page 5 of the present specification and also see the attached English abstract;

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JP 2002-543132 A is cited on page 5 of the present specification and also see the attached corresponding application WO 00/66122;

JP 2003-504397 A is cited on page 5 of the present specification and also see the attached corresponding application WO 01/05388 A2;

JP 10-265378 A is cited on page 5 of the present specification and was filed with the Information Disclosure Statement on April 5, 2006. See the attached English abstract;

JP 2001-89366 A is cited on page 5 of the present specification and was filed with Information Disclosure Statement on April 5, 2006. See the attached English abstract;

Hitoshi WATANABE, The Journal of the Eye, 1997, Vol. 14, No. 11, pp. 1647-1653 was filed with the Information Disclosure Statement on April 5, 2006. The partial English translation is attached;

Ikuko TODA et al.; The Journal of the Eye, 1991, Vol. 8, No. 7, pp. 1021-1027 was filed with the Information Disclosure Statement on April 5, 2006. The partial English translation is attached;

Satoshi SUZUKI et al., Nichigankaishi, 1997, Vol. 101, No. 1, pp. 52-56 was filed with the Information Disclosure Statement on April 5, 2006. The English abstract is attached;

Tsutomu INATOMI, Journal of Japan Contact Lens Society, 1999, Vol. 41, No. 4, pp. S7-S13 was filed with the Information Disclosure Statement on April 5, 2006. The English abstract is attached;

Murato Doru, The Japanese Journal of Ophthalmic Caring, May 1, 2003, Vol. 5, No. 5, pp. 406-410 was filed with the Information Disclosure Statement on April 5, 2006. The partial English translation is attached;

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Yong Liang ZHANG et al.; Colloid and Interface Science, Vol. 262, No. 1, pp. 130-148, June 1, 2003 was filed with the Information Disclosure Statement on April 5, 2006;

WO 01/51065 A1 was filed with the Information Disclosure Statement on April 5, 2006. See the attached English abstract;

JP 2003-313124 A was filed with the Information Disclosure Statement on April 5, 2006. See the attached English abstract.

☐ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached to the Information Disclosure Statement filed on April 5, 2006, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☐ d. OTHER - The following additional information is provided for the Examiner's consideration.

IV. FEES (check one box)

☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☒ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required.
(This section is not to be used with RCE's.)

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

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☐ e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

☐ f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.
or

☐ See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

☐ a. **Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or**

☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

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☐ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)

- ☐ The required fee is listed on the attached Fee Transmittal.
- ☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: JUL 5 2006

Respectfully submitted,

By 

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Attachment(s):

- ☒ PTO-SB08
- ☒ Documents
- ☐ Foreign Search Report
- ☐ Fee
- ☐ Other:



PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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|-------------------------------------------------------------------------------------------------------------------------------------------------|---|----|---|--------------------------|------------------|
| Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Complete if Known | |
| | | | | Application Number | 10/574,615 |
| | | | | Filing Date | April 5, 2006 |
| | | | | First Named Inventor | Yuzuru UMEDA |
| | | | | Art Unit | N/A |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 1 | of | 1 | Attorney Docket Number | 1691-0217PUS1 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|--------------------------|------------------------------------------|--------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| | AA* | US-5,116,868-A | 05-26-1992 | Chen et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|--------------------------|-----------------------------------------------------------------------------------|-----------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | BA | JP-10-265378-A | 10-06-1998 | | | ✓ |
| | BB | WO-01/51065-A1 | 07-19-2001 | | | |
| | BC | JP-2001-89366-A | 04-03-2001 | | | ✓ |
| | BD | JP-2003-313124-A | 11-06-2003 | | | |
| | BE | JP-6-345653-A | 12-20-1994 | | | ✓ |
| | BF | JP-2000-281563-A | 10-10-2000 | | | ✓ |
| | BG | WO-01/41806-A1 | 06-14-2001 | | | ✓ |
| | BH | JP-2002-543132-A | 12-17-2002 | | | ✓ |
| | BI | WO-00/66122-A1 | 11-09-2000 | | | ✓ |
| | BJ | JP-2003-504397-A | 02-04-2003 | | | ✓ |
| | BK | WO-01/05388-A2 | 01-25-2001 | | | ✓ |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² | |
| | CA | Hitoshi WATANABE, The Journal of the Eye, 1997, vol. 14, no. 11, pages 1647 to 1653 | ✓ | |
| | CB | Ikuko TODA et al., The Journal of the Eye, 1991, vol. 8, no. 7, pages 1021 to 1027 | ✓ | |
| | CC | Satoshi SUZUKI et al., Nichigankaishi, 1997, vol. 101, no. 1, pages 52 to 56 | | |
| | CD | Tsutomu INATOMI, Journal of Japan Contact Lens Society, 1999, vol. 41, no. 4, pages S7-S13 | | |
| | CE | Murato Doru, The Japanese journal of ophthalmic caring, 01 May, 2003, vol. 5, no. 5, pages 406 to 410 | ✓ | |
| | CF | ZHANG, Y.L. et al., Journal of Colloid and Interface Science, 01 June, 2003, vol. 262, no. 1, pages 130 to 148 | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.K./

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|-----------------------|------------------|--------------------|------------|
| Examiner Signature | /Sriram Kasturi/ | Date Considered | 07/10/2008 |
|-----------------------|------------------|--------------------|------------|